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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

JOHN PEARSON and STEPHANIE PEARSON, husband and wife, Plaintiff, v. WRIGHT MEDICAL TECHNOLOGY, INC., a foreign corporation, Defendant.	NO. 2:09-CV-00485-PHX-FJM **DEFENDANT WRIGHT MEDICAL TECHNOLOGY, INC.'S REPLY IN SUPPORT OF MOTION TO STRIKE THE TESTIMONY OF LESTER HENDRICKSON, PH.D. AND MOTION FOR SUMMARY JUDGMENT** **(Oral Argument Requested)**

Defendant Wright Medical Technology, Inc., through undersigned counsel, hereby submits its Reply in support of its Motion to Strike the testimony of Plaintiffs' metallurgy expert, Lester Hendrickson, Ph.D., and Motion for Summary Judgment. Dr. Hendrickson is not qualified to testify regarding the PROFEMUR® modular implant, and his opinions fail to satisfy the relevancy and reliability burdens required under *Daubert*.

Accordingly, Dr. Hendrickson should be precluded from testifying at trial and summary judgment should be entered in Defendant's favor.

This Reply is supported by the following Memorandum of Law, Defendant's Separate Statement of Facts previously submitted, the attached exhibits, the entire record before the Court, and any oral argument that may be heard in this matter.

MEMORANDUM OF LAW

I. INTRODUCTION

In their Response, Plaintiffs concede that Dr. Hendrickson reached his "expert" opinions based upon an erroneous and careless assumption concerning the type of hip implant at issue. Dr. Hendrickson admittedly failed to recognize that Mr. Pearson received a PROFEMUR® modular hip implant. Due to this fundamental mistake, Dr. Hendrickson reached irrelevant conclusions applicable to a significantly different type of medical device and ruled out fretting as a possible cause of failure. While it is not surprising that Dr. Hendrickson now attempts to excuse his embarrassing mistake and save Plaintiffs' case from dismissal, even his supplemental affidavit filed in support of Plaintiffs' Response is insufficient to defeat Defendant's Motion.

Defendant's Motion is not based solely on Dr. Hendrickson's reliance on the wrong medical device as Plaintiffs claim. The issue before the Court is whether a witness who lacks knowledge concerning a complex medical device, possesses no information about how the product is manufactured, has reviewed no product literature or manufacturing specifications, and has no explanation for an alleged product defect is nevertheless qualified under *Daubert* to offer expert testimony at trial in support of a manufacturing defect claim. For the reasons set forth in detail below, Dr. Hendrickson should not be permitted to testify at trial and Defendants' Motion for Summary Judgment should be granted.

II. LEGAL ARGUMENT

A. Dr. Hendrickson's General Experience As A Metallurgist Does Not Qualify Him To Testify As An Expert Concerning The PROFEMUR® Implant.

Plaintiffs argue it is "incredulous" for Defendant to suggest that Dr. Hendrickson is not qualified to offer expert testimony in this action. According to Plaintiffs, Dr. Hendrickson's experience as a metallurgist automatically qualifies him to testify concerning any product made of metal. This is incorrect. Although Dr. Hendrickson may indeed have expertise in certain areas of metallurgical analysis, he has no training or experience relevant to the manufacture of medical devices in general or the specific PROFEMUR® implant at issue in this litigation. To satisfy *Daubert*, it is essential that a proposed witness's qualifying training or experience, and resulting specialized knowledge, are sufficiently related to the issues and evidence before the trier of fact such that the witness's proposed testimony will be of assistance to the trier of fact. *In re Apollo Group, Inc. Securities Litigation,* 527 F.Supp.2d 957(D.Ariz.2007). For a court to recognize a witness as a qualifying expert, the subject of the testimony must lie within the purview of the witnesses's expertise. 4 Weinstein's Fed. Evid. § 702.06[1]; *Redman v. John D. Brush and Co.,* 111 F.3d 1174 (4th Cir.1997).

Numerous courts have considered and rejected the same argument Plaintiffs are making here. For example, in *Muller v. Synthes*, 2001 WL 521390 (N.D.Ill.), the plaintiffs disclosed a metallurgist to testify why a titanium cervical spine plate failed following surgery. Like Dr. Hendrickson, the expert metallurgist in *Muller* had no training or experience in the design of medical implants or any other medical devices. *Id*. The district court concluded that the metallurgist came "nowhere near satisfying the standards for expert testimony required under *Fed.R.Evid. 702*." *Id.* at *8. A similar result was reached in *Krueger v. Johnson and Johnson Prof'l, Inc.*, 160 F.Supp.2d 1026 (S.D.Iowa 2001). In *Krueger*, the plaintiff disclosed metallurgist George Otto to testify as an expert regarding a metal plate and screws that broke after spinal fusion surgery. Mr. Otto had a masters degree in metallurgy, was licensed as a professional engineer, and had

worked as a metallurgist for over forty-two years. Despite Mr. Otto's extensive experience in the field of metallurgy, the court in *Krueger* held that he was not qualified to offer opinions regarding the medical device at issue since he had no experience with medical implants and based his opinions on insufficient facts:

> In this case, Otto's qualifications and his proposed testimony do not satisfy the Rule 702 standard. First, like the metallurgist in *Muller*, **Otto has no experience in the design of medical implants or any other medical devices**. **Second, under subsection (a) of Rule 702, Otto's opinions are based on insufficient facts.** He does not know how much pressure it takes to bend a screw *in vivo* and has never been involved in the testing of a medical device to be used inside the body . . . The Court does not question Otto's understanding of the principles of metallurgy or his ability to apply those principles, but none of his testimony takes any consideration of the fact that this is a medical device which is inserted in a person's body. Any expert testimony in this case must be centrally connected with the fact that this is not a case where screws merely broke on a device, but the screws broke following the implantation of the device during a spinal surgery inside of a person's body. **None of the principles or methods used by Otto adequately reflect even a rudimentary understanding of the context in which this device was implanted** . . .

Krueger, 160 F.Supp.2d at 1031 (S.D.Iowa 2001) (emphasis added).

Dr. Hendrickson lacks the expertise necessary to assist the jury in this case. Like the expert opinions excluded in *Krueger*, Dr. Hendrickson's opinions are based upon insufficient facts and unsupported assumptions. He has admitted that he has no knowledge or information concerning the manufacturing process applicable to the PROFEMUR® implant. (SOF ¶ 23, 24). Dr. Hendrickson also failed to request or review any device manufacturing records, processing records, or performance specifications for the PROFEMUR® device prior to reaching his opinions, and has conceded that he has no opinion about how, when, or why the alleged manufacturing defect occurred. *Id.* Dr. Hendrickson's qualifications and proposed testimony fail to satisfy the Rule 702 admissibility standard in this case.

B. <u>Dr. Hendrickson's Expert Methodology Does Not Demonstrate Scientific Reliability.</u>

Plaintiffs do not dispute that an expert's methodology must demonstrate

scientific reliability in order to be admissible. *See* Fed.R.Evid. 702. *Daubert* establishes that an expert must employ a reasonable methodology in reaching his opinions. *Daubert*, 509 U.S. 579, 113 S.Ct. 2786 (1993). Courts may exclude expert testimony in instances where the methodology employed is either unreliable or entirely absent. *See*, e.g., *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156 (3rd Cir. 2000) (affirming district court's exclusion of expert testimony grounded on "haphazard, intuitive inquiry" instead of reliable methodology).

Dr. Hendrickson's opinions, including those set forth in his supplemental affidavit, are unreliable and not based upon any scientifically valid methodology. Dr. Hendrickson has admitted that he has "no idea" how the PROFEMUR® implant was manufactured or what caused the alleged manufacturing defect. (SOF ¶¶ 23, 24). Since the implant cracked, Dr. Hendrickson simply concluded that some unknown manufacturing defect must have occurred. As discussed in detail in Defendant's Motion, nearly identical speculative testimony was found to be scientifically invalid in the Arizona case of *Diviero v. Uniroyal Goodrich Tire Company*, 919 F.Supp. 1353 (D.Ariz. 1996). Similar testimony has also been rejected as unreliable in the context of medical device cases. In *Botnick v. Zimmer, Inc.,* 484 F.Supp.2d 715 (N.D.Ohio 2007), a products liability action was brought against the manufacturer of a metal bone plate that broke after being surgically implanted. The plaintiffs in *Botnick* disclosed a mechanical engineer, Leighton Sissom, to testify in support of their manufacturing defect claim. Like Dr. Hendrickson, Mr. Sissom admitted at his deposition that he had no understanding of how the subject device was manufactured. Although Mr. Sissom admitted that he was not familiar with the manufacturing process, he claimed he could "see the end result" of the product failure. *Id.* at 720. The court in *Botnick* excluded Mr. Sissom's testimony based on his lack of knowledge of the applicable manufacturing process and a flawed methodology:

> A review of Mr. Sissom's deposition testimony indicates that the methods he employed to reach his conclusions regarding the alleged defects in the Device fall short of the standard

> established in Rule 702 and *Daubert*. Mr. Sissom's methodology consisted of a review of the Scanning Electron Microscope ("SEM") photographs, a visual inspection which included **no testing, no inquiry into failure rates, no knowledge of the Device's manufacturing process and no explanation for the alleged defect.** Further, Mr. Sissom did not consult the manufacturing specifications and relevant industry standard – ASTM F 138 – to ascertain whether the Device was conforming . . . **Such an intellectual rigor and analysis is necessary before this Court can place any reliability on Mr. Sissom's expert testimony**.

Botnick, 484 F.Supp.2d at 720 (emphasis added).

As is *Botnick*, Dr. Hendrickson has admitted that he is unfamiliar with the manufacturing process for the PROFEMUR® implant, has not reviewed any of the manufacturing records or specifications, and has no explanation for what caused the alleged manufacturing defect to occur. (SOF ¶¶ 23, 24). In contrast, Defendants' metallurgy expert, Brad James, Ph.D., P.E., has extensive experience in the medical device industry, has reviewed the entire device history and development file for the PROFEMUR® implant, is familiar with the manufacturing process and specifications for the device, and performed a thorough and detailed examination of the failed implant at issue. (SOF ¶¶ 13-16; Exhibit A). Dr. James has also provided specific evidence supporting his conclusion that fretting, not a manufacturing defect, caused the PROFEMUR® implant to crack. Attached to this Reply as Exhibit A is an affidavit and presentation prepared by Dr. James supporting his conclusion that fretting was the cause of the implant failure. This presentation shows undeniable photographic evidence of the exact features that Dr. Hendrickson and Dr. James agree provide conclusive evidence of fretting – (1) linear, unidirectional wear markings; (2) pitting; and (3) debris. Dr. Hendrickson failed to look for these findings since he based his opinion on the wrong medical device and assumed there was no metal-to-mail contact as is required for fretting. The photographic evidence demonstrating the presence of fretting has not been, and cannot be, reasonably disputed.

C. Dr. Hendrickson's Testimony Fails To Meet The Relevancy Burden Set Forth In *Daubert*.

To be admissible under *Daubert*, Dr. Hendrickson's testimony must also exhibit relevancy, connecting his theory of an alleged defect in the PROFEMUR® implant to Mr. Pearson's injury. *Daubert*, 509 U.S. at 591-93, 113 S.Ct. at 2786. Daubert's relevance requirement stems from Rule 702's mandate that the testimony assist the trier of fact to understand the evidence or to determine a fact in issue. Thus, there must be a "fit" between the inquiry in the case and the testimony, and expert testimony that does not relate to any issue in the case is not relevant and therefore not helpful. *United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993) (citing *Daubert*). Mere conclusory allegations will not suffice. In *Botnick v. Zimmer*, the Court rejected the testimony of plaintiff's expert based upon such a lack of relevancy due to the fact that it was mere hypothesis:

> The evidence indicates that Mr. Sissom's theory of the alleged defect fails to meet the relevancy burden laid down in *Daubert*. Mr. Sisson testified that he reviewed photographs of the medical Device, but had **no familiarity with the manufacturing processes which generated the Device, alternative designs, or the use of the Device in the marketplace**. Moreover, Mr. Sissom testified that he did not test the device *in situ* or interrogate the stresses on the Device. **The Court finds Mr. Sissom's conclusory testimony is not driven, as it must be, by the context of the issues in this case. As this Court finds Mr. Sissom's expert opinion has no basis, other than mere hypothesis, his testimony will not be allowed before a jury**.

Botnick, 484 F.Supp.2d at 720 (emphasis added).

As in *Botnick*, Dr. Hendrickson's opinions are not relevant since he has no knowledge of the manufacturing process for the PROFEMUR® implant and is unfamiliar with how it functions when surgically implanted. Contrary to Plaintiffs' suggestion, a jury cannot infer that something must have gone wrong during the process of manufacturing the PROFEMUR® implant simply because it cracked after being surgically implanted. Inferences cannot be drawn out of "thin air"; instead, the proponent must adduce evidence of a factual predicate from which to draw inferences. *American*

Int'l Group, Inc. v. American Int'l Bank, 926 F.2d 829, 836 (9th Cir. 1991). That factual predicate is absent here. Dr. Hendrickson has failed to specify how, when, or why the alleged manufacturing defect occurred. His conclusions have no basis other than mere hypothesis and should not be allowed before the jury.

D. Defendant Did Not Admit Liability As Alleged By Plaintiffs.

Plaintiffs' final attempt to defeat Defendant's Motion is based upon Mr. Pearson's claim that a representative from Wright Medical Technology, Inc., Debbie Daurer, allegedly admitted liability immediately after the PROFEMUR® implant was discovered to have cracked. Although this allegation has no bearing on whether Dr. Hendrickson should be permitted to testify in support of Plaintiffs' manufacturing defect claim at trial, it is false and is contradicted by the affidavit of Ms. Daurer attached hereto as Exhibit B. Ms. Daurer is employed in the risk management department at Wright's corporate office in Tennessee. She is not a physician or metallurgist, and had no knowledge regarding what caused the implant to fail at the time she spoke with Mr. Pearson. This is supported by the following deposition testimony from Mr. Pearson explaining that Ms. Daurer requested during their initial telephone conversation that he send the cracked implant to Wright for examination:

> Q. Do you remember Ms. Dauer asking you to provide the actual prosthesis or the part that you had to Wright, so that they could investigate and look into it?
>
> A. Yes.

See Exhibit C, pg. 90, lns. 12-15. It defies logic that Ms. Daurer, who knew nothing about Mr. Pearson or his medical history, would immediately admit liability over the telephone while at the same time requesting that the failed implant be provided to her so it could be inspected and analyzed.

Assuming Ms. Daurer did admit that Wright was at fault during her telephone conversation with Mr. Pearson, which Defendant denies, any such statements would be inadmissible to prove Wright's liability under Rule 408 of the Federal Rules of Evidence. Rule 408 provides that statements made during compromise and settlement

negotiations are inadmissible to show a defendant's liability. According to Mr. Pearson's affidavit, Ms. Daurer stated during their initial conversation that she wanted to "make it right" and discussed compensating him for what had occurred. Any and all statements made by Ms. Daurer in connection with this discussion would be protected under Rule 408. Even if Mr. Pearson's allegations and representations are accepted as being true, which Defendant disputes, the context of the conversation was to discuss the possibility of settlement.

III. CONCLUSION

For the reasons set forth above, this Court should strike the testimony of Lester Hendrickson, Ph.D. and grant Defendants' Motion for Summary Judgment. Dr. Hendrickson has no knowledge concerning the PROFEMUR® implant, possesses no information about how the product is manufactured, has reviewed no product literature or manufacturing specifications, and has no explanation for how, when, or why the alleged manufacturing defect occurred. In the absence of Dr. Hendrickson's testimony, Plaintiffs cannot present specific facts or evidence showing that there are genuine issues of material fact remaining for trial.

DATED this 27th day of May, 2010.

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